IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 14-5076
	)	
2035, INC.,	)	
a corporation,	)	
and	)	**COMPLAINT FOR**
	)	**INJUNCTION**
ROBERT L. LYTLE,	)	
an individual, d/b/a	)	
2035 PMA and QLASERS PMA,	)	
	)	
Defendants.	)	

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 332(a), to enjoin 2035, Inc., a corporation, and Dr. Robert L. Lytle, an individual who also goes by the name Dr. Larry Lytle and does business as 2035 Private Membership Association ("2035 PMA") and QLasers Private Membership Association ("QLasers PMA") (hereafter collectively, "Defendants"), from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce of, articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), in that they are class III devices pursuant to 21 U.S.C. § 360c(f), and they are not the subjects of approved applications for premarket approval as

required by 21 U.S.C. § 360e(a), nor are they the subjects of an effective investigational device exemption under 21 U.S.C. § 360j(g); and

B. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce of, articles of device, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of the FDCA, 21 U.S.C. § 352(o), in that Defendants failed to provide notice or other information respecting Defendants' devices to FDA, as required by 21 U.S.C. § 360(k); and

C. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce of, articles of device, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of the FDCA, 21 U.S.C. § 352(a), in that the labeling for such devices is false and misleading; and

D. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce of, articles of device, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of the FDCA, 21 U.S.C. § 352(j), in that such devices are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in their labeling; and

E. 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), as described in paragraph A above, and misbranded within the meaning of 21 U.S.C. §§ 352(o), (a), and (j), as described in paragraphs B-D above, while such devices are held for sale after shipment in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant 2035, Inc., is incorporated under the laws of South Dakota. In May 2010, when FDA investigators from the Minneapolis District Office inspected Defendants' operations, 2035, Inc., was responsible for manufacturing QLaser devices, which it contracted out to Tri-Tech Manufacturing, Inc. ("Tri-Tech"), located in Rapid City, South Dakota. According to Defendant Lytle, since he created the entities 2035 PMA and QLasers PMA in 2010, 2035, Inc.'s activities have been limited to owning a cleared 510(k) notification for the QLaser Q1000 and QLaser 660 FlashProbe (510(k) notification K080513), holding patents to QLaser devices, and licensing such patents to 2035 PMA. Defendant 2035, Inc., is located at 2035 1st Avenue, Rapid City, South Dakota.

5. Defendant Robert L. Lytle is president of 2035, Inc., and the director of the 2035 PMA and QLasers PMA (discussed below). He has been manufacturing and distributing QLaser devices for over a decade, and authored the "Low Level Laser Application Guide," which Defendants distribute with their QLaser devices. Defendant Lytle has stated that he has the ultimate responsibility for the claims and labeling for the QLaser devices. Defendant Lytle holds seminars for the QLaser devices across the United States and distributes the QLaser devices nationwide. Defendant Lytle performs his duties at 2035 1st Avenue, Rapid City, South Dakota, and 3939 Canyon Lake Boulevard, Suite A, Rapid City, South Dakota.

6. The 2035 PMA is described by Defendant Lytle as a "private membership association." Verified Petition for a Declaratory Judgment Regarding Private Membership Associations at 4-5, *Lytle v. FDA et al.*, No. 5:13-cv-05083-JLV (Dec. 10, 2013) ("Verified Petition"). The 2035 PMA is responsible for developing the specifications for the devices in the QLaser System, and contracts with Tri-Tech to manufacture them. Tri-Tech receives components used to manufacture the QLaser devices in interstate commerce, including printed circuit boards from Colorado. The 2035 PMA is located at 2035 1st Avenue, Rapid City, South Dakota.

7. According to Defendant Lytle, QLasers PMA is also a "private membership association." Verified Petition at 4-5. QLasers PMA distributes QLaser devices nationwide. In addition, QLasers PMA holds QLaser seminars nationwide, solicits individuals to join Defendants' "private membership associations," and distributes Defendants' labeling and other materials. QLasers PMA is located at 3939 Canyon Lake Boulevard, Suite A, Rapid City, South Dakota.

DEFENDANTS' DEVICES

8. Defendants have been, and are now, manufacturing and distributing in interstate commerce various devices, as defined by 21 U.S.C. § 321(h), including, but not limited to the following: the Q10, Q1000, Q1000NG, Q1000NG+, 660 FlashProbe, 660 Enhancer Probe, 660NG Enhancer Probe, 660NG+ Enhancer Probe, 808 FlashProbe, 808 Enhancer Probe, 808NG Enhancer Probe, and 808NG+ Enhancer Probe.

9. Defendants' products are devices, within the meaning of 21 U.S.C. § 321(h), in that they are intended for use (a) in the cure, mitigation, treatment, or prevention of disease, and/or (b) to affect the structure or any function of the body of man, and do not achieve their

primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of their primary intended purposes.

10. Pursuant to Defendants' labeling, including the 2013 edition of the "Low Level Laser Application Guide" and www.qlaserspma.com, a website owned and operated by Defendant Lytle through QLasers PMA, the QLaser devices are intended for use in the treatment of "over 200 different diseases and disorders," including cancer, cardiac arrest, HIV/AIDS, diseases and disorders of the eye and ear, venereal disease, and diabetes. For example, Defendants' "Low Level Laser Application Guide" contains the following claims:

A. Cancer: "A doctor in California has developed a very successful cancer protocol using the QLaser System and Homeopathic detoxification of toxic metals, viruses, bacteria, and parasites all of which suppress the immune system. This program can be used by you in your own home for all stages of cancer. The doctor who developed this very successful protocol states IT IS NOT POSSIBLE TO HAVE CANCER WHEN YOU FOLLOW THIS PROTOCOL."

B. Cardiac Arrest: "Apply mode 2 of the Q1000NG directly over the heart immediately and then apply the 660 FlashProbe to acupoints. Reassure subject and coach in breathing rhythms. NEVER LEAVE HOME WITHOUT YOUR LASER BECAUSE YOU MAY SAVE YOUR OR SOMEONE ELSE'S LIFE."

C. HIV/AIDS: "Apply mode 1 of the Q1000NG to proprioceptive points 1-6 for one cycle daily, or as needed to control pain. Apply mode 1 of the Q1000NG to any sore muscles detected by palpation for 6-8 breaths for each site. If joints are painful, apply the 808 FlashProbe directly to the involved joint for one cycle. Re-apply to all sore areas."

D. Deafness: "Research demonstrates that deafness can be cured by alternately applying the 808 and 660 FlashProbes in the ears for one cycle daily for one month then 2-3 times a week for 6-12 months."

E. Macular Degeneration – Dry or Wet: "Go to www.laserfrequency.com and download special frequencies to your Q1000NG and apply over your eye 2-3 times a week for 6-8 breaths for 3 months, then apply weekly indefinitely."

F. Venereal Disease: "Apply the 660 FlashProbe directly to the lesion for 6-8 breaths. Move 1/2 inch and repeat until entire lesion has been treated. Repeat daily until improvement. If the above laser is not available sustitute [sic] mode 1 of the Q1000NG for one cycle per area and move as needed to cover entire area."

G. Diabetes: "Apply the Q1000NG and 660 FlashProbe as directed below every other day for 10 days and then once or twice a week as needed to control blood sugar. In some cases, it may be necessary to use this protocol the rest of your life."

11. All of Defendants' devices are classified as class III devices by statute, 21 U.S.C. § 360c(f), because they are intended for human use and they were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and they do not meet the exemptions set forth in 21 U.S.C. § 360c(f)(1).

12. Defendants distribute their devices throughout the United States. Components that comprise Defendants' devices are shipped from outside the state of South Dakota including, but not limited to, printed circuit boards from Colorado.

LEGAL STANDARDS

13. A class III device is adulterated if: (1) it is required to have in effect an approved application for premarket approval under 21 U.S.C. § 360e(a); (2) there is no FDA-approved

application for premarket approval in effect; and (3) it is not exempt from premarket approval as an investigational device under 21 U.S.C. § 360j(g). 21 U.S.C. § 351(f)(1)(B).

14. Virtually all devices introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, are automatically classified as class III as a matter of law, 21 U.S.C. § 360c(f)(1), and, with certain exceptions, must have an approved application for premarket approval prior to marketing. 21 U.S.C. §§ 360c(f)(1), 360e(a). The sponsor of a device may avoid this automatic statutory class III designation, and thereby avoid the premarket approval process, if it obtains an order from FDA reclassifying the device into class I or class II, or obtains from FDA a clearance that the device is "substantially equivalent" to a legally-marketed predicate device that does not require premarket approval (commonly known as a cleared 510(k) notification). 21 U.S.C. §§ 360c(f), 360e(a) and (b), 360(k).

15. The introduction or delivery for introduction into interstate commerce of an adulterated device is a violation of the FDCA, 21 U.S.C. § 331(a).

16. A 510(k) notification is required for any device that is: (a) being introduced into commercial distribution for the first time (21 C.F.R. § 807.81(a)(1)); or (b) currently in commercial distribution, but has a significant change or modification in its intended use (21 C.F.R. § 807.81(a)(3)(ii)).

17. A device is misbranded if a person introduces such device into interstate commerce for commercial distribution without submitting to FDA a 510(k) notification. 21 U.S.C. § 352(o).

18. A device is misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a).

19. A device is also misbranded if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in its labeling. 21 U.S.C. § 352(j).

20. The introduction or delivery for introduction into interstate commerce of a misbranded device is a violation of the FDCA, 21 U.S.C. § 331(a).

21. The adulteration or misbranding of a device while it is held for sale after shipment in interstate commerce is a violation of the FDCA, 21 U.S.C. § 331(k).

EVIDENCE OF DEFENDANTS' VIOLATIVE CONDUCT

22. Most recently, in August and September 2014, FDA investigated Defendants' business operations, including QLasers PMA, and www.qlaserspma.com, a website owned and operated by Defendant Lytle through QLasers PMA. These investigations revealed that Defendants continue to make claims that cause their QLaser devices to be adulterated and misbranded within the meaning of the FDCA, as detailed in paragraph 23 below. Specifically, screenshots of www.qlaserspma.com captured during the investigator's review of this website demonstrate that it contains claims that the QLaser devices cure, mitigate, treat, or prevent numerous diseases, including cancer, heart disease, diseases and disorders of the eye and ear, herpes, and diabetes. Pamphlets received from QLasers PMA during the August/September 2014 investigations, including the "QLaser 'Personal Proof' Questionnaire" and "QLaser: The Q Series Low Level Lasers," contain similar claims, including claims that the QLaser devices cure, mitigate, treat, or prevent cancer, heart disease, diseases and disorders of the eye and ear, herpes, and diabetes.

23. From September 10 to 13, 2013, after obtaining warrants for administrative inspection signed by United States Magistrate Judge Veronica L. Duffy, FDA investigators from

the Minneapolis District Office inspected 2035, Inc., 2035 PMA, and QLasers PMA. These inspections revealed numerous violations of the FDCA and its implementing regulations, including Defendants' distribution in interstate commerce of adulterated and misbranded devices. Specifically, the FDA investigators documented the following violations with respect to one or more of Defendants' devices:

A. Defendants manufacture and distribute numerous class III devices for which they do not have in effect an approved application for premarket approval pursuant to 21 U.S.C. § 360e(a) or a cleared 510(k) notification pursuant to 21 U.S.C. §.360(k), nor do they have an effective investigational device exemption under 21 U.S.C. § 360j(g).

1. By letter dated January 30, 2009, FDA cleared Defendants' Q1000 and 660 FlashProbe for "providing temporary relief of pain associated with osteoarthritis of the hand, which has been diagnosed by a physician or other licensed medical professional" (510(k) notification K080513).

2. Defendants' labeling contains numerous claims that were not cleared in 510(k) notification K080513. For example, Defendants' labeling states that the QLaser System, which includes the Q1000 and 660 FlashProbe, treats hundreds of diseases and conditions, including cancer, cardiac arrest, HIV/AIDS, diseases and disorders of the eye and ear, venereal disease, and diabetes. These claims go well beyond "providing temporary relief of pain associated with osteoarthritis of the hand" and therefore constitute a major change or modification in the devices' cleared intended use, requiring the submission of a new 510(k) notification(s), or possibly an application for premarket approval. 21 C.F.R. § 807.81(a)(3). FDA has not received any new 510(k) notifications, or applications for premarket approval, for the Q1000 or the 660 FlashProbe.

3. Defendants do not have approved applications for premarket approval or cleared 510(k) notifications for the following devices: Q10, Q1000NG, Q1000NG+, 660 Enhancer Probe, 660NG Enhancer Probe, 660NG+ Enhancer Probe, 808 FlashProbe, 808 Enhancer Probe, 808NG Enhancer Probe, and 808NG+ Enhancer Probe.

B. Defendants cause the labeling of the devices they manufacture to be false and misleading.

1. For example, Defendants' Low Level Laser Application Guide claims that the QLaser System treats "over 200 different diseases and disorders," including cancer, cardiac arrest, HIV/AIDS, diseases and disorders of the eye and ear, venereal disease, and diabetes.

2. There are no published clinical studies demonstrating that the QLaser devices treat these diseases, or any of the other diseases listed in the Low Level Laser Application Guide.

3. In addition, Defendants claim their QLaser devices are "harmless," which they are not. For example, Defendants promote their devices to treat eye diseases, including myopia and macular degeneration; however, applying any of Defendants' devices to the eye could result in temporary or permanent damage.

4. Defendants' 660 and 808 lines of QLaser devices are, pursuant to the Federal Laser Product Performance Standard, 21 C.F.R. Part 1040, class IIIb lasers, and "class IIIb levels of laser radiation are considered to be an *acute hazard* to the skin and eyes from direct radiation." 21 C.F.R. § 1040.10(b)(9) (emphasis added).

C. Defendants are manufacturing and distributing devices that are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

1. For example, Defendants' labeling establishes that the Q1000 line of QLaser devices are intended for use in the treatment of conditions of the eye, including myopia and macular degeneration. Direct application of any of these devices to the eye could result in injury, including temporary or permanent blindness.

2. In addition, Defendants' labeling instructs users of the 808 line of QLaser devices to apply the laser beams of these devices directly to the skin. Applying a device from the 808 line of QLaser devices directly to the skin could cause damage to the skin, including burns.

24. At the conclusion of the September 2013 inspections, FDA investigators issued to Defendant Lytle two Forms FDA-483, List of Inspectional Observations detailing Defendants' violations of the FDCA.

PRIOR INSPECTIONS

25. FDA previously inspected or attempted to inspect Defendant Lytle and his businesses four times from 2001 to 2012.

26. Between December 4 and 6, 2012, FDA attempted to inspect 2035, Inc. During the attempted inspection, Defendant Lytle refused to provide information related to the activities being performed by 2035, Inc., stating to the FDA investigators that he could not comment on the activities of his private membership association because the investigators were not members and because the activities of his "private membership associations" are outside the jurisdiction of the FDA.

27. Between May 25 and 27, 2010, an investigator from FDA's Minneapolis District Office inspected 2035, Inc. During this inspection, the FDA investigator collected documentary samples, which included, among other things, samples of Defendants' labeling. Defendants' labeling contained, among other things, the following statements regarding the QLaser devices: treats "tendonitis, arthritis, burns . . . and any pain or inflammation"; "speed[s] bone repair"; "help[s] repair damaged DNA"; "repolarize[s] damaged cell walls"; and "[is] a multi-organ cell-reenergizer . . . proven effective and beneficial for healing, and to benefit inflammation or disorders of all internal, and the treatment of any unknown condition."

28. In May 2007, an investigator from FDA's Minneapolis District Office contacted Defendant Lytle to request information about his current activities involving the QLaser System. In a voicemail left on the FDA investigator's cell phone, Defendant Lytle, apparently believing the call to have terminated, states to an unknown person that if the FDA investigator questions him about businesses or his laser devices, he will tell the FDA investigator that he makes "low level lasers for a veterinary type of thing."

29. Defendants have been and are violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce of, devices that are adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), as set forth above in paragraphs 23.

30. Defendants have been and are violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce of, devices that are misbranded within the meaning of 21 U.S.C. §§ 352(o), (a), and (j), as set forth above in paragraph 23.

31. Defendants have been and are violating 21 U.S.C. § 331(k), by causing the devices to become adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), and misbranded within the meaning of 21 U.S.C. §§ 352(o), (a), and (j), while such devices are held for sale after shipment in interstate commerce, as set forth above in paragraph 23.

PRIOR NOTICE OF VIOLATIONS

32. Defendants are well aware that their practices violate the FDCA. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the FDCA.

33. On March 3, 2011, following the May 2010 inspection of 2035, Inc., FDA issued a Warning Letter to Defendants Lytle and 2035, Inc. The Warning Letter informed Defendant Lytle that documents collected during the May 2010 inspection, as well as FDA's review of Defendants' websites, established that the QLaser devices were devices within the meaning of the FDCA, 21 U.S.C. § 321(h), because they were "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . or are intended to affect the structure or any function of the body." The Warning Letter also informed Defendant Lytle that his QLaser devices were adulterated and misbranded within the meaning of the FDCA because Defendants, in the case of the Q10 and 808 Enhancer Probe, failed to submit to FDA a 510(k) premarket notification or application for premarket approval, and, in the case of the Q1000 and 660 FlashProbe (which the Warning Letter mistakenly identified as the 660 Enhancer Probe), made major changes or modifications to the cleared intended use, without submitting a new 510(k) notification or an application for premarket approval. The Warning Letter notified Defendants that failure to correct the cited deviations could result in further action including injunction.

34. In response to the May 2010 inspection and March 2011 Warning Letter, Defendant Lytle sent FDA a series of letters challenging its jurisdiction over his distribution of the QLaser devices through his "private membership associations" and demanding that it "rescind" the March 2011 Warning Letter. FDA replied in writing that the formation of such "private membership associations" did not obviate Defendant Lytle's obligation to comply with the law. In November 2011, Defendant Lytle sued Gerald Berg, then-Director of FDA's Minneapolis District Office, and Timothy Philips, Compliance Officer. *Lytle v. Berg et al.*, No. 11-cv-5089 (D.S.D. Nov. 14, 2011). On September 24, 2013, Judge Viken of the United States District Court for the District of South Dakota dismissed this lawsuit. *Lytle v. Berg et al.*, No. 11-cv-5089, slip op. at 17 – 18. On April 1, 2013, the United States Court of Appeals for the Eighth Circuit affirmed. *Lytle v. Berg et al.*, 500 Fed. App'x 562 (8th Cir. 2013).

35. In August 2002, FDA sent Defendant Lytle an Untitled Letter, informing him that his products were medical devices and, as such, he was required by law to obtain marketing clearance or approval before offering them for sale in interstate commerce.

36. By letter dated October 28, 2002, Defendant Lytle responded to the Untitled Letter, claiming that his devices were veterinary devices and promising to, among other things, "eliminate" many of the statements contained in his labeling.

37. Despite numerous warnings from FDA since 2001, Defendants continue to violate the FDCA, as documented during FDA's August/September 2014 investigations and September 2013 inspections.

38. Based on Defendants' continued illegal conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k).

WHEREFORE, Plaintiff prays:

I. That Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be restrained and enjoined pursuant to 21 U.S.C. § 332(a) from directly or indirectly:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce of, any article of device that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), or misbranded within the meaning of 21 U.S.C. §§ 352(o), (a), or (j); and

B. violating 21 U.S.C. § 331(k), by causing any article of device to become adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), or misbranded within the meaning of 21 U.S.C. §§ 352(o), (a), or (j), while such article is held for sale after shipment in interstate commerce.

II. That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly or indirectly manufacturing, packing, labeling, and/or distributing any device, unless and until Defendants ensure that, for each model of device designed, manufactured, and distributed, they have obtained premarket approval or clearance from FDA and that the device is designed, manufactured, and distributed in accordance with such approval or clearance.

III. That the Court authorize FDA, pursuant to this injunction, to inspect Defendants' place of business to ensure continuing compliance with the terms of this injunction, with the

costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Respectfully submitted,

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